

K241921 Alinity m BKVMar 24, 2025
266 days to decisionK241921 · Product code: **QMI** · Microbiology
Source: <https://www.510kdatabase.net/k241921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Amplification Test For The Quantitation Of Bk Virus (bk) Dna (QMI)
Date received	Jul 1, 2024
Decision date	Mar 24, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Molecular, Inc.
Location	Des Plaines, IL, US
Contact	Gina Sammarco
510(k) history	17 submissions · 16 cleared · 2008-2025

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